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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,480	04/02/2004	Claudio P. Plaza	51991/AW/W112	7287
23363 7590 10/12/2007 CHRISTIE, PARKER & HALE, LLP PO BOX 7068 PASADENA, CA 91109-7068			EXAMINER VRETTAKOS, PETER J	
			ART UNIT 3739	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/820,480

Applicant(s)

PLAZA, CLAUDIO P.

Examiner

Peter J. Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is final.

The application is published application number: 2005/ 0222564. The publication is classified in US 606/41.

The effective filing date of this application is 4-2-04.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moaddeb et al. (6,405,078) in^o view of Skalsky et al. (4,844,099).

The instant application shares figures and law firm with Moaddeb.

Moaddeb discloses a catheter for mapping and stimulation of cardiac tissue with a tip electrode (36), electromagnetic sensor (64,72), temperature sensor (claim 41) and irrigation tube (38).

However, the reference is silent regarding a non-conductive porous material (sintered ceramic or sintered polyethylene) and a conductive porous coating (platinum-iridium) as claimed.

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Skalsky et al. discloses an impant (see figure 24) for mapping and stimulation of cardiac tissue with a tip electrode (148a,b) and a non-conductive porous material (sintered ceramic or sintered polyethylene; 140; 60 in col. 5:56-64) and a conductive porous coating (platinum-iridium 66 in col. 6:28-32; 148).

Skalsky discloses a tip electrode (fig. 3) comprising a non-conductive porous material (60) and a conductive porous coating/electrode leaves (66). It can be fairly asserted that the non-conductive porous material is configured to avoid "substantial" contact with the tissue. (Added 3-30-07).

The combination of the two patents suggest a tip electrode catheter with a non-conductive porous material and a conductive porous coating *as claimed*. The motivation to combine the patents is to reduce costs due to platinum-iridium price and is found in Skalsky col. 2:34-39 where the patent mentions the high cost of stimulation electrodes (made of platinum iridium). This presupposes that the amount in platinum iridium in figure 24 Skalsky is appreciably less than that in figure 9 of Maddeb.

Therefore, at the time of the invention in would have been obvious to one of ordinary skill in the art to modify Moaddeb in view of Skalsky by integrating into the Moaddeb tip electrode design the non-conductive porous material and conductive porous coating of Skalsky. Again, the motivation to combine the patents is to reduce costs due to

platinum-iridium price and is found in Skalsky col. 2:34-39 where the patent mentions the high cost of stimulation electrodes (made of platinum iridium).

The combination of the two patents makes obvious:

1. An irrigated electrode catheter (Moaddeb figure 9 and Skalsky figure 24) comprising: a catheter body (see Moaddeb figure 1) having proximal and distal ends and a lumen (Moaddeb 35) extending therethrough; a tip section (Moaddeb 36) having proximal and distal ends, the proximal end of the tip section being fixedly attached to the distal end of the catheter body (see Moaddeb figure 1); a porous tip electrode (Moaddeb 36) fixedly attached to the distal end of the tip section, the tip electrode comprising a non-conductive porous material (Skalsky figure 24 element 140) and a conductive porous (Moaddeb col. 6:52-55 – **porous** platinum-iridium) coating (Skalsky platinum-iridium 148b) adapted to cover the non-conductive porous material; and an irrigation tube (Moaddeb 38) extending through the catheter body and into the porous tip electrode of the tip section, whereby fluid passing through the irrigation tube can pass through the non-conductive porous material and the conductive porous coating to reach surrounding tissue.
2. An irrigated electrode catheter according to claim 1, further comprising an electrode lead wire (Moaddeb 44) in electrical communication with the conductive porous coating.

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3. An irrigated electrode catheter according to claim 1, wherein the non-conductive porous material is made from material selected from the group consisting of polyethylene, Teflon and ceramic. See Skalsky col. 5:56-65.

4. An irrigated electrode catheter according to claim 1, wherein the non-conductive porous material comprises polyethylene. See Skalsky col. 5:56-65.

5. An irrigated electrode catheter according to claim 1, wherein the conductive porous coating is made from material selected from the group consisting of platinum and gold. See Skalsky col. 6:28-32.

6. An irrigated electrode catheter according to claim 1, wherein the conductive porous coating comprises an alloy of platinum and iridium. See Skalsky col. 6:28-32.

7. An irrigated electrode catheter according to claim 6, wherein the alloy of platinum and iridium comprises 90% platinum and 10% iridium. See Moaddeb col. 6:54-57.

8. An irrigated electrode catheter according to claim 1, wherein fluid passes through channels between particles of the non-conductive porous material. See Skalsky figure 5 elements 60 and 68.

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9. An irrigated electrode catheter according to claim 1, wherein fluid passes through channels of a webbing (See Skalsky "leaves") of the conductive porous coating.

10. An irrigated electrode catheter according to claim 1, further comprising a temperature sensing means (Moaddeb claim 41) mounted within the tip electrode.

11. An irrigated electrode catheter according to claim 1, further comprising an electromagnetic sensor (Moaddeb 64, 72) mounted in the tip section.

12. An irrigated electrode catheter according to claim 1, wherein the non-conductive porous material comprises sintered polymer particles. See Skalsky col. 5:56-64.

13. An irrigated electrode catheter according to claim 1, wherein the non-conductive porous material comprises sintered ceramic particles. See Skalsky col. 5:56-64.

14. An irrigated electrode catheter according to claim 12, wherein the polymer particles comprises particles of polyethylene or Teflon. See Skalsky col. 5:56-64.

15. An irrigated electrode catheter (see above) comprising: a catheter body (see above) having an outer wall, proximal and distal ends, and a lumen (see above) extending therethrough; a tip section (see above) comprising a segment of flexible tubing having proximal and distal ends and at least one lumen therethrough, the proximal end of the

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tip section being fixedly attached to the distal end of the catheter body; a porous tip electrode (see above) fixedly attached to the distal end of the tubing of the tip section, the tip electrode having an outer surface and comprising a non-conductive porous material (see above) through which fluid can pass and a **thin metal coating** (aka "conductive porous coating" see above) adapted to cover the non-conductive porous material; and an irrigation tube (see above) having proximal and distal ends extending through the central lumen in the catheter body, wherein the distal end of the irrigation tube is in fluid communication with the proximal end of the passage in the tip electrode, whereby fluid can pass through the irrigation tube, into the passage in the tip electrode and through the porous material of the tip electrode to the outer surface of the tip electrode.

16. An irrigated electrode catheter according to claim 15, further comprising an electrode lead wire (see above) in electrical communication with the thin metal coating.

17. An irrigated electrode catheter according to claim 15, wherein the non-conductive porous material is made from material selected from the group consisting of polyethylene, Teflon and ceramic. (See above.)

18. An irrigated electrode catheter according to claim 15, wherein the non-conductive porous material comprises polyethylene. (See above.)

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19. An irrigated electrode catheter according to claim 15, wherein the thin metal coating is made from material selected from the group consisting of platinum and gold. (See above.)

20. An irrigated electrode catheter according to claim 15, wherein the thin metal coating comprises an alloy of platinum and iridium. (See above.)

21. An irrigated electrode catheter according to claim 20, wherein the alloy of platinum and iridium comprises 90% platinum and 10% iridium. (See above.)

22. An irrigated electrode catheter according to claim 15, wherein fluid passes through channels between particles of the non-conductive porous material. (See above.)

23. An irrigated electrode catheter according to claim 15, wherein fluid passes through channels of a webbing of the thin metal coating. (See above.)

24. An irrigated electrode catheter according to claim 15, further comprising a temperature sensing means mounted within the tip electrode. (See above.)

25. An irrigated electrode catheter according to claim 15, further comprising an electromagnetic sensor mounted in the tip section. (See above.)

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26. An irrigated electrode catheter according to claim 15, wherein the non-conductive porous material comprises sintered polymer particles. (See above.)

27. An irrigated electrode catheter according to claim 15, wherein the non-conductive porous material comprises sintered ceramic particles. (See above.)

28. An irrigated electrode catheter according to claim 26, wherein the polymer particles comprises particles of polyethylene or Teflon. (See above.)

29. An irrigated electrode catheter comprising: a catheter body; a tip section attached to the catheter body;
a porous tip electrode fixedly attached to the tip section, the tip electrode comprising a non-conductive porous material and a conductive porous coating generally encapsulating the non-conductive porous material;
and an irrigation tube extending through the catheter body and into the porous tip electrode of the tip section, whereby fluid passing through the irrigation tube can pass through the non-conductive porous material and the conductive porous coating to reach surrounding tissue. Addressed above.

30. An irrigated electrode catheter comprising: a catheter body;
a tip section attached to the catheter body; a porous tip electrode fixedly attached to the tip section, the tip electrode comprising an inner (116 is centralized in figure 16) non-

conductive porous material and an outer (112c are dispersed along the outer periphery of the electrode in figure 16) conductive porous material; and an irrigation tube extending through the catheter body and into the porous tip electrode of the tip section, whereby fluid passing through the irrigation tube can pass through the non-conductive porous material and the conductive porous coating to reach surrounding tissue. Addressed above.

Response to Arguments

Applicant's arguments filed 8-6-07 have been fully considered but they are not persuasive. The Applicant provides two arguments to why the rejection(s) should be obviated. Both arguments are arbitrary and provide no objective rationale with which the Examiner can rely in reasons for allowance.

First, the phrase "configured to avoid substantial contact with tissue" is wholly subjective and arbitrary. Is the phrase defined in the Applicant's specification? What is "substantial"? What amount of contact is considered substantial...substantial with respect to what? The Examiner cannot withdraw a rejection based upon a term that ill-defined in prosecution and varies as dictated by the definition applied to it.

Second, the Applicant's arguments about Skalsky not disclosing conductive material covering/encapsulating/being outside of non-conductive material presupposes one is describing the distal tip of the skalsky device in the axial direction. This is an arbitrary presupposition. If one arbitrarily describes Skalsky with respect to its circumferential axis (view the device circumferentially, start from the center (such as

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148b in figure 25) and move radially outward), then a fair assertion is that Skalsky discloses a conductive material (112) covering/encapsulating/being outside of non-conductive material (116) in figure 15.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pete Vrettakos
October 5, 2007



ROY D. GIBSON
PRIMARY EXAMINER